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Dated: June 1, 2009
Electronic Signature for Stephen J. Brown: /Stephen J. Brown/

Docket No.: LOREAL 3.0-039

(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Fares, *et al.*

Application No.: 10/646,300

Group Art Unit: 1617

Filed: August 22, 2003

Examiner: K.A. Cruz

For: COMPOSITIONS CONTAINING TOPICAL
ACTIVE AGENTS AND PENTYLENE
GLYCOL

APPELLANTS' REPLY BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is in reply to the Examiner's answer filed on March 31, 2009.

The rejection in this case is based on obviousness. Yet, the Examiner's obsessive refusal to consider the data establishing unexpected results, contained in both the present specification and in the Fares Declaration, has led to a complete blurring of the line between anticipation and obviousness.

The Examiner apparently realizes that the mere fact that *Castro*, within its four corners, includes a reference to both 1,2-pentanediol and hydrocortisone, clearly does not convert this reference into one which is anticipatory. The claimed compositions of this invention are not specified in *Castro*. Nonetheless, the Examiner goes on to conclude that based on the teachings in *Castro* "it is not an unreasonable stretch for one of ordinary skill in the art of cosmetics and dermatological

compositions to understand that *Castro* fairly teaches a composition with hydrocortisone and a pentylene glycol." (P.8 emphasis added.) Based on this assertion, the Examiner then goes on to conclude with regard to the Fares Declaration:

Thus that Declaration is not persuasive because *Castro* clearly teaches a pentylene glycol. The unexpected results presented in the specification . . . would have also been present in the composition of *Castro* and would not have been surprising or unexpected. "A chemical composition and its properties are inseparable. Therefore, **if the prior art teaches the identical chemical structure**, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The fact that hydrocortisone is more soluble in pentylene glycol than other glycols would have been observed by *Castro*.

In essence, the Examiner's position amounts to an allegation of inherent anticipation; i.e., since the claimed compositions are now suggested to be "anticipated" by the prior art, the properties of those compositions were inherent.

There is, however, no basis whatsoever for the Examiner to allege that *Castro* anticipates claim 16 or any of the claims herein. Furthermore, the obviousness rejection can be properly overcome by the presentation of unexpected results. The Examiner has committed clear error by refusing to consider this evidence.

The Examiner then asserts that she has, in fact, allegedly considered the Fares Declaration, but that it "does not address the primary reference of *Castro* who teaches a pentylene glycol."

This makes no sense. The Examiner thus appears to require that Appellants compare the claimed compositions to themselves, that is, to the compositions of *Castro* modified as suggested by the rejection. Such a comparison defies logic, let alone being contrary to law. M.P.E.P. § 716.02(e)(III) makes it clear that the claimed invention must be compared to the closest prior art

reference, not to nonexistent art such as that which might be contemplated by a modification of a reference or a combination of references:

Although evidence of unexpected results must compare the claimed invention with the closest prior art, **applicant is not required to compare the claimed invention with subject matter that does not exist in the prior art.** *In re Geiger*, 815 F.2d 686, 689, 2 USPQ2d 1276, 1279 (Fed. Cir. 1987) (Newman, J., concurring) (Evidence rebutted *prima facie* case by comparing claimed invention with the most relevant prior art. Note that the majority held the Office failed to establish a *prima facie* case of obviousness.); *In re Chapman*, 357 F.2d 418, 148 USPQ 711 (CCPA 1966) (**Requiring applicant to compare claimed invention with polymer suggested by the combination of references relied upon in the rejection of the claimed invention under 35 U.S.C. 103 "would be requiring comparison of the results of the invention with the results of the invention."** 357 F.2d at 422, 148 USPQ at 714.).

(M.P.E.P. at 700-297 (emphasis added).) The evidence of unexpected results presented by the Appellants involves a comparison of the claimed invention to comparative compositions closer to the claimed compositions than those taught by the primary reference, *Castro*.

Specifically, the inventive compositions were compared to comparative compositions containing hydrocortisone and other solvents, including homologous glycols disclosed in *Cooper* and *Quigley*. Therefore, the comparative compositions are believed to be closer to the claimed compositions than are the compositions taught by *Castro*. Comparative results of this type are clearly probative of nonobviousness:

Applicants **may compare the claimed invention with prior art that is more closely related to the invention than the prior art relied upon by the examiner.** *In re Holladay*, 584 F.2d 384, 199 USPQ 516 (CCPA 1978); *Ex parte Humber*, 217 USPQ 265 (Bd. App. 1961) (Claims to a 13-chloro substituted compound were rejected as obvious over nonchlorinated analogs of the claimed compound. Evidence showing unexpected results for the claimed

compound as compared with the 9-, 12-, and 14-chloro derivatives of the compound rebutted the *prima facie* case of obviousness because the compounds compared against were closer to the claimed invention than the prior art relied upon.).

(M.P.E.P. § 716.02(e) (p. 700-296 (emphasis added)).)

As explained in the Appeal Brief, the submitted data demonstrate that hydrocortisone is more soluble in pentylene glycol than in hexylene glycol, propylene glycol, or butylene glycol, and that the release rate of hydrocortisone from a gel of the present invention was about 100 times greater than the various commercial products tested, none of which contained pentylene glycol. At least three benefits can be attributed to these properties of the combination of pentylene glycol and hydrocortisone and its derivatives — aesthetic appeal, less tackiness, and greater bioavailability of the hydrocortisone. As Dr. Fares also explains, the latter property is also believed to be exactly opposite to that suggested by Vollhardt, which is primarily focused on increasing retention of sunscreen agents on the skin. As attested to by Dr. Fares in his Declaration, these results would not have been expected based on the collective teachings of the prior art. Accordingly, it is submitted that these unexpected results establish that the claimed invention is nonobvious and patentable over the cited prior art.

In conclusion, Appellants' evidence of unexpected results has not been properly considered and given fair weight in the

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obviousness determination. Therefore, Appellants request that the rejection be reversed.

Dated: June 1, 2009

Respectfully submitted,
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